K111275

510(k) Summary

FEB 0 1 2013

DATE PREPARED January 29, 2013

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical ASD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Julie Tapper Senior Regulatory Affairs Specialist
Common/Usual Name:	Ambulatory Infusion Pump Pump Communications System
Proprietary Name:	CADD®-Solis VIP Ambulatory Infusion Pump CADD™-Solis Medication Safety Software
Predicate Devices:	K072144, CADD®-Solis Ambulatory Infusion Pump K960826, CADD-Prizm® VIP Ambulatory Infusion Pump K082783, CADD™-Solis Medication Safety Software—Point of Care K072144, CADD™-Solis Medication Safety Software—Administrator

II. DEVICE DESCRIPTION

CADD®-Solis VIP Ambulatory Infusion Pump

The CADD®-Solis VIP Ambulatory Infusion Pump ("Solis VIP Pump") has a microprocessor and linear peristaltic pumping mechanism, similar in design to the Smiths Medical ASD, Inc. CADD®-Solis Ambulatory Infusion Pump (K072144) and CADD-Prizm® VIP Ambulatory Infusion Pump (K960826). The user activates the Solis VIP Pump via a color LCD screen and keypad user interface. Commands are issued to the microprocessor by activating the user interface. Microprocessor actions are controlled by a program, which is contained in the pump's memory.

The Solis VIP Pump consists of components, such as the user interface, sensors, communication ports, power ports, structural (housing) components, electronics, pumping mechanism, watchdog timer, pump battery and circuitry, real time clock, on-board memory, and pump log. The Solis VIP Pump exterior surface components include the pump housing, LCD lens, labels, and keypad, and the materials of construction for these components are widely used in the medical industry. The Solis VIP Pump is designed to be used with an infusion disposable, such as medication cassette reservoir.

The Solis VIP Pump provides measured drug therapy to patients in the hospital, homecare, and outpatient settings. The Solis VIP Pump is intended for therapies that require a Continuous, Intermittent, Tapering, or Step rates of infusion, and Patient Controlled Analgesia (including Clinician Bolus).

CADD™-Solis Medication Safety Software—Administrator

The CADD™-Solis Medication Safety Software—Administrator ("Administrator") module allows the user to create, edit, and save therapy-based protocols and pump settings within user-defined protocol libraries. The system administrator user determines user access and library editing capabilities. Other Administrator module features include barcode printing, reports, and sending and receiving pump protocol information.

CADD™-Solis Medication Safety Software—Point of Care

The CADD™-Solis Medication Safety Software—Point of Care ("POC") module allows the user to download therapy based protocols to the Solis Pump, and Prizm Pump (software revision H or higher) and send and receive pump settings via USB connection.

III. INTENDED USE OF THE DEVICE

CADD®-Solis VIP Ambulatory Infusion Pump

The CADD®-Solis VIP Ambulatory Infusion Pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, perineural, surgical site, epidural space, or subarachnoid space infusion.

PCA (patient-controlled analgesia) delivery is used for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both, such as patient-controlled analgesia.

Continuous delivery allows the infusion of drug/fluid at a constant, programmed rate.

Intermittent delivery allows the infusion of a specific volume of drug/fluid at a regular, programmed interval.

Step delivery allows an incremental increase in infusion rate to a specified maximum infusion rate for a specified total infusion volume.

Taper delivery allows a plateau rate of infusion with the option of tapering at the beginning and/or end and has a programmable KVO rate at the end of the infusion.

CADD™-Solis Medication Safety Software—Administrator

The CADD™ Solis Medication Safety Software – Administrator allows use of a computer to create therapy-based protocol libraries to be used with the CADD®-Solis VIP Ambulatory Infusion Pump, CADD®-Solis Ambulatory Infusion Pump or CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher).

CADD™-Solis Medication Safety Software—Point of Care:

The CADD™ Solis Medication Safety Software—Point of Care allows use of a computer to send therapy-based protocols developed by the CADD™-Solis Medication Safety Software—Administrator to the CADD®-Solis Ambulatory

Infusion Pump and CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher).

VI. SUMMARY OF STUDIES

Performance Testing

Smiths Medical performed extensive verification and validation testing on the Solis VIP Pump and Administrator and POC software.

Testing was completed in accordance with FDA's draft guidance, *Total Product Life Cycle—Infusion Pump – Premarket Notification [510(k)] Submissions*, issued on April 23, 2010; and the *General Principles of Software Validation; Final Guidance for Industry and FDA Staff*, issued on January 11, 2002.

Also, testing was completed in accordance with FDA consensus standards, *IEC 60601-1:1988 Medical electrical equipment - Part 1: General requirements for safety,* plus *Amendment 1:1991, Amendment 2:1995* and *Amendment 2 Corrigendum:2005*, and *IEC 60601-2-24:1998 - Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers.*

An overall summary of the performance testing was, as follows:

Electrical and mechanical safety tests	Electromagnetic compatibility tests
Solis VIP Pump software validation	Administrator and POC software validation
Usability/human factors validations for the Solis VIP Pump and Administrator and POC Software	Infusion disposable biocompatibility testing, including extractables and leachables

Clinical Studies

Human clinical studies were deemed unnecessary to evaluate the safety or effectiveness of the Solis VIP Pump, and Administrator and POC software.

Testing Conclusion

All testing met pre-established specifications, and successfully demonstrated that the devices performed as intended. The testing results allowed for a conclusion to be made that the Solis VIP Pump, and Administrator and POC software were as safe and effective as the predicate devices.

VII. STATEMENT OF EQUIVALENCE

The Solis VIP Pump, and Administrator and POC software are substantially equivalent to the predicate devices, based on comparisons of the device classifications, intended use, and technological characteristics. Verification and validation tests confirmed the suitability of the devices for their intended uses. The test results did not raise new safety or performance questions, and confirmed that the Solis VIP Pump, and Administrator and POC software devices are substantially equivalent to the predicate devices.

V. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS

CADD®-Solis VIP Ambulatory Infusion Pump			
Device name	CADD®-Solis VIP Ambulatory Infusion Pump	CADD®-Solis Ambulatory Infusion Pump	CADD-Prizm® VIP Ambulatory Infusion Pump
Manufacturer	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.
510(k) notification number (Substantial equivalence date)	K111275 (TBD)	K072144 (March 7, 2008)	K960826 (May 23, 1996)
SYSTEM FEATURES			
Pump type	Linear Peristaltic	Linear Peristaltic	Linear Peristaltic
Display	Color display with 320 x 320 pixels	Color display with 320 x 320 pixels	Monchromatic display with 32 x 128 pixel, dot matrix
Power requirements	4AA Batteries AC Adapter Rechargeable Battery Pack	4AA Batteries AC Adapter Rechargeable Battery Pack	1-9 volt Battery EPS AC Adapter EPS Power Pack
Printing capabilities	No	No	Yes
Remote communications capabilities	No	No	No
USB port	Yes	Yes	No
PROGRAMMING FUNCTIONS			
Step	Yes	No	No
Intermittent	Yes	No	Yes
Taper	Yes	No	Yes (TPN)
Continuous infusion	Yes	Yes	Yes
Continuous infusion with bolus (PCA)	Yes	Yes	Yes
Security	Yes	Yes	Yes
Demand dose lockout	Yes	Yes	Yes
Delivery limit	Yes	Yes	Yes
Programmable titration limits	Yes	Yes	Yes
Titration feature available while running	Yes	Yes	Yes
Programmable KVO	Yes	No	Yes
Programmable maximum rate	Yes	Yes	Yes
Epidural mode	Yes	Yes	Yes
ALARMS			
Low battery	Yes	Yes	Yes
Depleted battery	Yes	Yes	Yes
External power source low	Yes	Yes	Yes

CADD®-Solis VIP Ambulatory Infusion Pump			
Device name	CADD®-Solis VIP Ambulatory Infusion Pump	CADD®-Solis Ambulatory Infusion Pump	CADD-Prizm® VIP Ambulatory Infusion Pump
No-battery alert	Yes	Yes	Yes
Pump in stop mode	Yes	Yes	Yes
High pressure	Yes	Yes	Yes
Power up fault	Yes	Yes	Yes
Low volume in medication reservoir	Yes	Yes	Yes
Cassette detachment	Yes	Yes	Yes
Upstream occlusion	Yes	Yes	Yes
Downstream occlusion	Yes	Yes	Yes
Air-in-line	Yes	Yes	Yes
Key stuck	Yes	Yes	Yes
INFUSION SPECIFICATIONS			
Minimum continuous delivery rate	0 mL/hr	0 mL/hr	0 mL/hr
Maximum continuous delivery rate	100 mL/hr in PCA 500 mL/hr in Continuous, Intermittent, Taper, Step	30 mL/hr	30 mL/hr in PCA 350 mL/hr in Continuous, Intermittent, TPN
Maximum patient bolus	50 mL	20 mL	9.9 mL
Maximum clinician bolus	50 mL	20 mL	20 mL
Reservoir volume	1 to 9999 mL	1 to 9999 mL	1 to 9999 mL
Patient controlled access PCA (dosing)	Yes	Yes	Yes
Dose lockout time	Yes	Yes	Yes
Doses per hour limit	Yes	Yes	Yes
Delivery limit	Yes	Yes	Yes
Clinician bolus	Yes	Yes	Yes
Programmable maximum delivery rate (Continuous rate + bolus)	Yes	Yes	Yes

CADD™-Solis Medication Safety Software Administrator and POC			
Device Name	CADD™-Solis Medication Safety Software (software update)	CADD™-Solis Medication Safety Software (software update)	CADD™-Solis Medication Safety Software
Manufacturer	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.	Smiths Medical ASD, Inc.
510(k) notification number (substantial equivalence date)	K111275 (TBD)	K082783 (December 17, 2008)	K072144 (March 7, 2008)
COMPATIBILITY			
Pump compatibility	CADD®-Solis VIP Ambulatory Infusion Pump, CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II 6101 (rev H and higher)	CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II 6101 (rev H and higher)	CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II 6101 (rev H and higher)
Accessory compatibility	USB cable for the CADD®-Solis VIP pump, and CADD®-Solis pump 21-6144 Interface cable/null modem cable for CADD-Prizm® pump	USB cable for the CADD®-Solis pump 21-6144 Interface cable/null modem cable for CADD-Prizm® pump	USB cable for the CADD®-Solis pump 21-6144 Interface cable/null modem cable for CADD-Prizm® pump
PC software compatibility	Windows 2000, XP, VISTA	Windows 2000, XP, VISTA	Windows 2000, XP, VISTA
Computer equipment	RS232 serial port, USB, and CD-ROM	RS232 serial port, USB, and CD-ROM	RS232 serial port, USB, and CD-ROM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Febauary 1, 2013

Ms. Julie Tapper
Senior Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
1265 Grey Fox Road
ST. PAUL, MN 55112

Re: K111275
Trade/Device Name: CADD® -Solis VIP Ambulatory Infusion Pump and CADD™-Solis Medication Safety Software
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: January 21, 2013
Received: January 22, 2013

Dear Ms. Tapper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

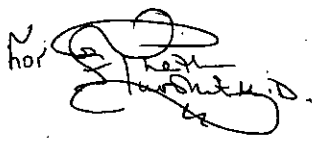
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours;



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SMITHS MEDICAL ASD, INC.
510(k) Premarket Notification
CADD®-Solis VIP Ambulatory Infusion Pump
CADD™-Solis Medication Safety Software

Indications for Use

510(k) Number: K111275

Device Name: **CADD®-Solis VIP Ambulatory Infusion Pump**

Indications for Use:

"The CADD®-Solis VIP Ambulatory Infusion Pump is indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, perineural, surgical site, epidural space, or subarachnoid space infusion.

PCA (patient-controlled analgesia) delivery is used for therapies that require a continuous rate of infusion, patient-controlled demand doses, or both, such as patient-controlled analgesia.

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Step delivery allows an incremental increase in infusion rate to a specified maximum infusion rate for a specified total infusion volume.

Taper delivery allows a plateau rate of infusion with the option of tapering at the beginning and/or end and has a programmable KVO rate at the end of the infusion."

Prescription Use ___X___ OR Over-The Counter Use _____Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Date: 2013.02.01 13:20:30 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____

SMITHS MEDICAL ASD, INC.
510(k) Premarket Notification
CADD®-Solis VIP Ambulatory Infusion Pump
CADD™-Solis Medication Safety Software

Indications for Use

510(k) Number: K111275

Device Name: **CADD™ Solis Medication Safety Software – Administrator**

Indications for Use:

"The CADD™ Solis Medication Safety Software – Administrator allows use of a computer to create therapy-based protocol libraries to be used with the CADD®-Solis VIP Ambulatory Infusion Pump, CADD®-Solis Ambulatory Infusion Pump or CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher)."

Prescription Use ___X___ OR Over-The Counter Use _____ Per 21 CFR 801.109

Device Name: **CADD™ Solis Medication Safety Software – Point of Care**

Indications for Use:

"The CADD™ Solis Medication Safety Software – Point of Care allows use of a computer to send therapy-based protocols developed by the CADD™-Solis Medication Safety Software – Administrator to the CADD®-Solis Ambulatory Infusion Pump and CADD-Prizm® PCS II Ambulatory Infusion Pump (software revision H or higher)."

Prescription Use ___X___ OR Over-The Counter Use _____ Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2013.01.30 10:21:19 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____